Translation

PATENT COOPERATION TREATY

PCT/JP2003/008524

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K4-A0201P	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/008524	International filing date (*day/month/year*) 04 July 2003 (04.07.2003)	Priority date (*day/month/year*) 04 July 2002 (04.07.2002)
International Patent Classification (IPC) or national classification and IPC A61K 39/215, 39/395, 48/00, A61P 31/12, C12Q 1/68, G01N 33/569 // C12N 15/09		
Applicant THE KITASATO INSTITUTE		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) Disc 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 30 January 2004 (30.01.2004)	Date of completion of this report 04 November 2004 (04.11.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/008524

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/JP03/08524

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

JP0308524

Document 1: "Comparison of the Amino Acid Sequence and Phylogenetic Analysis of the Promoter, Integral Membrane and Nucleocapsid Proteins of Feline, Canine and Porcine Coronaviruses," (K. Motokawa, et al.), Microbiol. Immunol., 1996, Vol. 40, No. 6, pages 425-433

Document 2: WO, 97-20054, A1 (Virogenetics Corp.), 5 June, 1997 (05.06.97), & AU; 9712780, B, & EP, 868522, A1, & US, 5858373, A, & JP, 2000-501930, A

Document 3: EP, 652287, A2 (American Home Products Corp.), 10 May, 1995 (10.05.95), & AU, 9474116, B, & CA, 2132374, A1, & JP, 7-184662, A, & US, 5656275, A, & US, 5770211, A

Document 4: EP, 376744, A1 (American Home Products Corp.), 4 July, 1990 (04.07.90), & AU, 8946915, B, & CA, 2005291, A1, & JP, 2-291273, A, & US, 5780266, A, & US, 5811104, A

Document 5: "Primary Structure of the Membrane and Nucleocapsid Protein Genes of Feline Infectious Peritonitis Virus and Immunogenicity of Recombinant Vaccinia Viruses in Kittens," (H. Vennema, et al.), Virology, 1991, Vol. 181, No. 1, pages 327-335

Document 6: JP, 2000-302692, A (Kyoritsu Shoji Co.), 31 October, 2000 (31.10.00) (Family: none)

Document 7: US, 6241989, A (Cornell Research Foundation Inc.), 5 June, 2001 (05.06.01), whole document, the claims, Example 8, SEQ ID NO: 18 (Family: none)

Document 8: EP, 411684, A1 (Duphar International Research B.V.), 6 February, 1991 (06.02.91), & CA, 2020740, A1, & JP, 3-164182, A

Document 9: Database Medline ON stn, No. 96112252, "Protection of Cats from Infectious Peritonitis by Vaccination with a Recombinant Raccoon Poxvirus Expressing Nucleocapsid Gene of Feline Infectious Peritonitis Virus," (T. L. Wasmoen, et al.), Adv. Exp. Med. Biol., 1995, Vol. 380, pages 221-228

Document 10: WO, 95-8575, A1 (Cornell Research Foundation Inc.), 30 March, 1995 (30.03.95) (Family: none)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/JP03/08524

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: "Comparison of the Amino Acid Sequence and Phylogenetic Analysis of the Promoter, Integral Membrane and Nucleocapsid Proteins of Feline, Canine and Porcine Coronaviruses," (K. Motokawa, et al.), Microbiol. Immunol., 1996, Vol. 40, No. 6, pages 425-433

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Document 3: EP, 652287, A2 (American Home Products Corp.), 10 May, 1995 (10.05.95), & AU, 9474116, B, & CA, 2132374, A1, & JP, 7-184662, A, & US, 5656275, A, & US, 5770211, A

Document 4: EP, 376744, A1 (American Home Products Corp.), 4 July, 1990 (04.07.90), & AU, 8946915, B, & CA, 2005291, A1, & JP, 2-291273, A, & US, 5780266, A, & US, 5811104, A

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Document 10: WO, 95-8575, A1 (Cornell Research Foundation Inc.), 30 March, 1995 (30.03.95) (Family: none)

INTERNATIONAL PRELI[redacted]ARY REPORT ON PATENTABILITY

I[redacted]tional application No.
PCT/JP03/08524

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: V2

[A] None of documents 1-10 cited in the ISR describes the subject matters of claims 1-3, 5 and 6, particularly the constitution in which if either the N protein derived from type I FIPV strain KU-2 or a gene vector having the gene encoding the said N protein expressibly integrated is employed as an active ingredient of a vaccine, an advantageous therapeutic and/or preventive effect for the diseases infected with FIPV can be seen without showing any special increase of the neutralizing antibody titer on the one hand and without enhancing the FIPV infection potentiation by anti-FIPV antibodies on the other hand. This constitution is not considered to be obvious to a person skilled in the art from these documents either.

The technical idea per se of employing the N protein derived from FIPV as an active ingredient of a vaccine was known to a person skilled in the art before the priority date of the present application, as described in documents 2-9. So, it is desirable to give a supplementary explanation in the examples (pages 41-54) of the specification of the present application about the matter that the vaccine containing the N protein derived from strain KU-2 as an immunogen exhibits a remarkable effect in FIP improvement compared with the respective vaccines as the state of the prior art disclosed in any one of documents 2-9.

[B] None of documents 1-10 cited in the ISR describes the subject matter of claim 4, especially the constitution in which if an antibody capable of being bound to the N protein derived from type I FIPV strain KU-2 is employed as an active ingredient, an advantageous FIP therapeutic and/or preventive effect can be actually exhibited without accompanying the potentiation of infection by the said antibody per se, etc. This constitution is not considered to be obvious to a person skilled in the art from these documents either.

The examples of the specification of the present application do not show the data that (1) a fraction containing an antibody against the N protein derived from strain KU-2 was particularly produced from the serum of an animal immunized by the said N protein, or (2) the said antibody-containing fraction actually contributed to the action relating to the said FIP therapy and/or prevention. Furthermore, in the immunized animals of the respective examples, no clear correlation can be confirmed between the degree of the effect relating to the said therapy and/or prevention and the degree of the anti-N protein neutralizing antibody titer in the serum either. Therefore, it is desirable to give a supplementary explanation to ensure that it can be particularly identified from the description of the specification or drawings of the present application that (1) the said antibody-containing fraction can be particularly produced based on the description of the specification or drawings of the present application, and (2) the said antibody-containing fraction actually contributes to the therapeutic and/or preventive effect. Moreover, to allow the inventive step of the subject matter of claim 4 to be understood sufficiently, it is also desirable to give a supplementary explanation about the matter that the antibody as the active ingredient specified in claim 4 is especially different in the FIP therapeutic and/or preventive effect compared with the monoclonal antibody described in either the following document (1) or (2) showing the state of the prior art relating to the anti-FIPV N protein monoclonal antibodies, referred to in the specification (page 39) of the present application:

(1) "Antigenic Analysis of Feline Coronaviruses with Monoclonal Antibodies (MAbs): Preparation of MAbs which discriminate between FIPV strain 79-1146 and FECV strain 79-1683," (T. Hohdatsu, et al.), Vet. Microbiol., 1991, Vol. 28, No. 1, pages 13-24

(2) "Characterization of Monoclonal Antibodies against Feline Infectious Peritonitis Virus Type II and Antigenic Relationship between Feline, Porcine, and Canine Coronaviruses," (T. Hohdatsu, et al.), Arch. Virol., 1991, Vol. 117, No. 1-2, pages 85-95

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: V2

[C] None of documents 1-10 cited in the ISR describes the subject matters of claims 7 and 8, especially the constitution in which if the N protein derived from Type I FIPV strain KU-2 is employed as an active ingredient for drugs used to examine FIPV infection, examination drugs capable of reacting well also with the serum infected with feline coronaviruses other than strain KU-2 can be obtained as disclosed in the specification of the present application ([10], Fig. 18). This constitution is not considered to be obvious to a person skilled in the art from these documents either.